DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
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VIA FEDERAL EXPRESS

April 16, 2004

James G. Shepherd, President
KBD, Inc.
20 Kenton Lands Road
Erlanger, KY 41018

WARNING LETTER CIN-04-21336

Dear Mr. Shepherd:

An inspection of your medical device manufacturing firm located in Erlanger, KY conducted by our investigator from March 9-12, 2004, revealed that the devices manufactured at that facility, class II phototherapy lamps, are adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The deviations from the QSR include, but are not limited to, the following:

Management Controls

Failure to establish adequate management control to ensure that an effective quality system has been established and maintained. [21 CFR 820.20] For example:

- A management representative has not been appointed to ensure that quality system requirements are effectively maintained and to report on the performance of the quality system to management with executive responsibility for review. [21 CFR 820.20(b)(3)] Specifically, the previous management representative permanently left your firm in May 2003. A new representative has not been appointed.

- Quality system procedures have not been established for all quality subsystems. [21 CFR 820.20(e)] For example, there are no procedures for corrective and preventive actions, or controlling the design process.

- Management with executive responsibility has not ensured that the quality policy is understood at all levels of the organization. [21 CFR 820.20(a)] Specifically, two out of three employees questioned did not know your quality policy. One of these did not know where the policy could be located.

- Adequate resources have not been provided for performing management activities, assessment activities, and audits. [21 CFR 820.20(b)(2)] You stated that time and money

allocations towards quality assurance were difficult and that you have yet to replace the management representative who left your firm ten months ago.

- Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. [21 CFR 820.22] Specifically, the most recent quality audit was conducted in 1997.

- Failure to adequately train personnel to perform their assigned responsibilities. [21 CFR 820.25(b)] Specifically, no quality or manufacturing employees have been trained on the quality system regulations.

Corrective and Preventive Actions

- Failure to establish procedures for implementing corrective and preventive actions, including failure to document corrective and preventive activities, including analysis of quality data sources, investigations of causes of non-conformances, and implementation of corrective and preventive actions. [21 CFR 820.100]

- Complete complaint files are not maintained. [21 CFR 820.198(a) (3)] Specifically, the complaint procedure does not address reviewing communications about parts not working properly. You stated that you do not consider communications regarding broken or defective units as complaints.

Design Controls

- Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. [21CFR 820.30] Specifically, you do not have any procedures to control changes to the medical devices that you manufacture.

Production and Process Controls

- Failure to document the disposition of nonconforming product. [21 CFR 820.90(b)(1)]. Specifically, you are not following your "Non-Conforming Material" and your "Manufacturing Discrepancy Reporting" procedures.

- Failure to document the calibration of equipment used to test the phototherapy lamps. [21 CFR 820.72(a)] Specifically, records were not available for the mercury dispenser or the slaughter tester.

Records

- The device master record does not include or refer to the location of all production and process specifications. [21 CFR 820.181(b)] Specifically, you do not have a device master record for the psoriasis phototherapy lamp, PH-36 a class II medical device.

- Procedures have not been established to ensure that the device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality System Regulation. [21 CFR 820.184] Specifically, there are no device history records covering particular phototherapy lamps and sunlamps manufactured by your firm.

Acceptance Activities

- Acceptance records were not maintained as part of the device history record. [21 CFR 820.80(e)] Specifically, you do not keep records of the finished device test performed on Class II Phototherapy Lamps.

Identification and Traceability

- Procedures for identifying product throughout all stages of receipt, production, packaging, distribution and installation were not implemented. [21 CFR 820.60] Specifically, you were not following your procedure for "Bulb Inventory Control".

Handling, Storage, Distribution

- Failure to apply device control numbers to distribution records as required by your procedures [21 CFR 820.160(b)]. Specifically, the glass code date is not being applied to the packing slips as required by your procedures.

Document Controls

- Procedures and other documents required by the Quality System Regulation do not contain the signature of the approving official or the date of approval [21 CFR 820.40(a)]. Specifically, at least six procedures relating to manufacturing and/or testing of products do not bear the signature or date.

You should know that deficiencies listed above are serious violations of the law. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil monetary penalties.

Neither this letter nor the FDA-483 that was issued at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your facility. As president of KBD Inc., it is your responsibility to assure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

We acknowledge your letter dated March 15, 2004 responding to the FDA-483 Observations. Our review of the letter finds that it is inadequate in addressing all of the deficiencies listed on the FDA-483. Other than stating that you will hire an additional employee, it does not list any other specific steps you will be taking to correct your firm's deficiencies.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the deviations listed above. In addition, please submit any additional documentation to show the corrections initiated in conformance with the requirements of the Quality System Regulation. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certifications to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Your written response to this Warning Letter should be sent to Mr. Stephen J. Rabe, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Mr. Rabe at (513) 679-2700, extension 163, or you may forward a facsimile to him at (513) 679-2773.

Sincerely,

Deborah Gnelle

/S/ Carol A. Heppe
District Director
Cincinnati District